

CLAIMS:

1. A peptide or polypeptide comprising an Fv molecule, a construct thereof, a fragment of either, or a construct of a fragment having enhanced binding characteristics so as to bind selectively and/or specifically to a target cell in favor of other cells, wherein the binding selectivity or specificity is primarily determined by a first hypervariable region, and wherein the Fv is a scFv or a dsFv, and optionally having one or more tags.
2. The peptide or polypeptide of claim 1, wherein the first hypervariable region is a CDR3 region having an amino acid sequence selected from the group consisting of SEQ ID NOs:8-24.
3. The peptide or polypeptide of claim 1 wherein the first hypervariable region is a CDR3 region having an amino acid sequence selected from the group consisting of SEQ ID NOs:8-24, and wherein the binding selectivity or specificity is secondarily influenced by a second hypervariable region, by a third hypervariable region, and/or by one or more of the upstream or downstream region flanking the first, the second and/or the third hypervariable regions.
4. The peptide or polypeptide of claim 2 wherein the peptide or polypeptide is a scFv having SEQ ID NO: 25 in which the first hypervariable region is a CDR3 region which is identical to SEQ ID NO: 8.
5. The peptide or polypeptide of claim 1 wherein the scFv molecule comprises a straight or branched chain spacer of 20 or fewer amino acid residues.
6. The peptide or polypeptide of claim 5 wherein the spacer comprises SEQ ID NO: 123 or SEQ ID NO: 124.

7. The peptide or polypeptide of claim 1 wherein the target cell is an activated, excited, modified, changed, disturbed, abnormal or diseased cell.
8. The peptide or polypeptide of claim 7, wherein the diseased cell is a cancer cell.
9. The peptide or polypeptide of claim 7 wherein the cell is selected from the group consisting of carcinoma, sarcoma, leukemia, adenoma, lymphoma, myeloma, blastoma, seminoma, and melanoma cells.
10. The peptide or polypeptide of claim 9 wherein the cell is a leukemia or myeloma cell.
11. The peptide or polypeptide of claim 9 wherein the leukemia or myeloma cell is a B-cell malignancy.
12. The peptide or polypeptide of claim 10, wherein the leukemia cell is an acute myeloid leukemia cell or a B-cell malignancy.
13. The peptide or polypeptide of claim 2 further comprising a cassette of consecutive amino acids having an amino acid sequence selected from the group consisting of SEQ ID NOs:30-113, or having at least 90% amino acid similarity therewith, or fragment thereof, wherein the cassette or fragment provides a framework into which is built, inserted, attached coupled, combined, or fused a CDR3 region having an amino, acid sequence selected from the group consisting of SEQ ID NOs:8-24.
14. The peptide or polypeptide of claim 13 wherein the cassette has an amino acid sequence selected from the group consisting of SEQ ID NOs:30-32,33, 37-39,41, 43, 45, 46, 48, 51, 54, 57, 59-68, 70, 71, 76-85, 87, 89-92, 94, 97,

99, 103, 106, 112, and 113, or having at least 90% amino acid similarity therewith.

15. The peptide or polypeptide of claim 13 wherein the cassette has the amino acid sequence of SEQ ID NO: 61, or has at least 90% amino acid similarity therewith.
16. The peptide or polypeptide of claim 15, wherein the cassette has the amino acid sequence of SEQ ID NO: 61, or has at least 90% amino acid similarity therewith.
17. The peptide or polypeptide of claim 15, wherein the seven carboxy-terminal amino acid residues of SEQ ID NO: 61 are replaced by the seven amino acid residues of SEQ ID NO: 122.
18. The peptide or polypeptide of claim 3, wherein the second and third hypervariable regions are a CDR2 and a CDR1 hypervariable region, respectively.
19. The peptide or polypeptide of claim 2, wherein the CDR3 region has the amino acid sequence SEQ ID NO: 8.
20. The peptide or polypeptide of claim 18 wherein the CDR2 and CDR1 regions have the amino acid sequences SEQ ID NO: 115 and SEQ ID NO: 114, respectively.
21. The peptide or polypeptide of claim 3, wherein the second and third hypervariable regions are a CDR2 and CDR1 hypervariable region respectively and wherein the CDR3, CDR2 and CDR1 regions have the amino acid sequences SEQ ID NOs:8, 115 and 114, respectively.

22. The peptide or polypeptide of claim 3, wherein the upstream region flanking the CDR3 region has the amino acid sequence of SEQ ID NO: 117, and wherein the downstream region flanking the CDR3 region has the amino acid sequence of SEQ ID NO: 116.
23. The peptide or polypeptide of claim 3, wherein the second hypervariable region is a CDR2 hypervariable region and wherein the upstream region flanking the CDR2 region has the amino acid sequence of SEQ ID NO: 119, and wherein the downstream region flanking the CDR2 region has the amino acid sequence of SEQ ID NO: 118.
24. The peptide or polypeptide of claim 3 wherein the third hypervariable region is a CDR1 hypervariable region and wherein the upstream region flanking the CDR1 region has the amino acid sequence of SEQ ID NO: 121, and wherein the downstream region flanking the CDR1 region has the amino acid sequence of SEQ ID NO: 120.
25. The peptide or polypeptide of claim 18 wherein the CDR2 and CDR1 regions of a cassette of consecutive amino acids selected from the group consisting of SEQ ID NOs:30-113 or a fragment thereof are replaced by SEQ ID NOs:115 and 114, respectively.
26. The peptide or polypeptide of claim 18, wherein the CDR2 and CDR1 regions of a cassette of consecutive amino acids selected from the group consisting of SEQ ID NOs:30-32, 35, 37-39, 41, 43, 45, 46, 48, 51, 54, 57, 59-68, 70, 71, 76-85, 87, 89-92, 94, 97, 99, 103, 106, 112, and 113 or a fragment thereof are replaced by SEQ ID NOs:115 and 114, respectively.
27. The peptide or polypeptide of claim 3 wherein

the second and third hypervariable regions are a CDR2 and a CDR1 hypervariable region, respectively,

the CDR3 amino acid sequence is SEQ ID NO: 8,

the CDR2 amino acid sequence is SEQ ID NO: 115,

the CDR1 amino acid sequence is SEQ ID NO: 114,

the upstream region flanking the CDR3 region has the amino acid sequence of SEQ ID NO: 117,

the downstream region flanking the CDR3 region has the amino acid sequence of SEQ ID NO: 116,

the upstream region flanking the CDR2 region has the amino acid sequence of SEQ ID NO: 119,

the downstream region flanking the CDR2 region has the amino acid sequence of SEQ ID NO: 118,

the upstream region flanking the CDR1 region has the amino acid sequence of SEQ ID NO: 121, and

the downstream region flanking the CDR1 region has the amino acid sequence of SEQ ID NO: 120.

28. The peptide or polypeptide of claim 1 wherein the Fv is an scFv obtainable from a phage display library.

29. The peptide or polypeptide of claim 28, wherein the phage display library was constructed from peripheral blood lymphocytes of a non-immunized human, and wherein the scFv peptide is selected against previously uncharacterized and unpurified antigens on the surface of a target cell.
30. A method for selecting or identifying the peptide or polypeptide of claim 28 comprising biopanning, wherein the biopanning comprises binding phage to a target, removing non-bound phage, eluting bound phage, and propagating and amplifying eluted phage.
31. A peptide or polypeptide comprising an Fv molecule, a construct thereof, a fragment of either, or a construct of a fragment, having enhanced binding characteristics so as to bind selectively and/or specifically to a substantially exposed and/or over-expressed binding site on or in a target cell, wherein the binding to the target cell occurs in favor of other cells on or in which the binding site is not substantially available and/or expressed, wherein the binding selectivity or specificity is primarily determined by a first hypervariable region, wherein the Fv is a scFv or a dsFv, and wherein the FV optionally has one or more tags.
32. The peptide or polypeptide of claim 31, wherein the first hypervariable region is a CDR3 region having an amino acid sequence selected from the group consisting of SEQ ID NOs:8-24.
33. The peptide or polypeptide of claim 31 wherein the first hypervariable region is a CDR3 region having an amino acid sequence selected from the group consisting of SEQ ID NOs:8-24, and wherein the binding selectivity or specificity is secondarily influenced by a second hypervariable region, by a third hypervariable region, and/or by one or more upstream or downstream region flanking the first, the second and/or the third hypervariable regions,

and wherein the second and third hypervariable regions are a CDR2 and a CDR1 region, respectively.

34. A peptide or polypeptide comprising an Fv molecule, a construct thereof, a fragment of either, or a construct of a fragment having enhanced binding characteristics so as to bind selectively and/or specifically to a target cell in favor of other cells, wherein the Fv molecule comprises a first chain having a first, a second and a third hypervariable region and a second chain having a first, a second and a third hypervariable region, wherein one of the hypervariable regions of the first chain has a sequence selected from the group consisting of SEQ ID NOs:8-24, and wherein one of the hypervariable regions of the second chain has a sequence selected from the group consisting of SEQ ID NOs:1-6 and 125-202, and wherein the first, second and third hypervariable regions are a CDR3, CDR2 and CDR1 region, respectively, wherein the Fv is a scFv or a dsFv, and wherein the Fv optionally has one or more tags.

35. The peptide or polypeptide of claim 34 wherein

the first chain and the second chain each comprises a first hypervariable region selected from the group consisting of SEQ ID NOs:8-24; or

the first hypervariable region of the first chain and the first hypervariable region of the second chain are identical and are selected from the group consisting of SEQ ID NOs:8-24; or

the first hypervariable region of the first chain is selected from the group consisting of SEQ ID NOs:8-24, and the first hypervariable region of the second chain is selected from the group consisting of SEQ ID NOs:1-6 and 125-202; or

the first hypervariable region of the first chain is selected from the group consisting of SEQ ID NOs:1-6 and 125-202, and the first hypervariable region of the second chain is selected from the group consisting of SEQ ID NOs:8-24.

36. The peptide or polypeptide of claim 34, wherein the second and third hypervariable regions of the first chain are SEQ ID NOs:114 and 115, respectively.
37. A peptide or polypeptide comprising an Fv molecule, a construct thereof, a fragment of either or a construct of a fragment that
- binds to an unknown ligand on a first cell having a first and a second state, wherein the binding is effective in the second state but is not substantially effective in the first state, and
- by virtue of immuno-cross-reactivity, binds specifically or selectively to a ligand on a second cell, and wherein the Fv is a scFv or a dsFv and wherein the Fv optionally has one or more tags.
38. The peptide or polypeptide of claim 37, wherein the first cell is a normal cell.
39. The peptide or polypeptide of claim 37, wherein the first state is a non-activated state and the second state is an activated, excited, modified, changed or disturbed state.
40. The peptide or polypeptide of claim 37, wherein the second cell is a diseased cell.
41. The peptide or polypeptide of claim 40, wherein the diseased cell is a cancer cell.